Concepts, Objectives and Generalized Structure for Developing a SETAC Weight-of-Evidence (WoE) Guidance Document

SETAC Expertise in WoE

SETAC scientists from around the world have been leaders in the development of applying various WoE approaches to scientific decision-making that involves consideration of known lines of evidence (LOEs), where a "weight" is systematically assigned to each LOE based upon the relevance and reliability associated with the evidence related to each LOE. Although the concept of using WoE has been in the practice of law for many years, SETAC recognized very early on that there was a need to standardize definitions and methods in this area in particular as it applies to the use of WoE for ecological risk assessment and chemical management strategies and policy. SETAC formalized attention to the WOE concept in 2015 with the organization of a SETAC Pellston Workshop: Improving the Usability of Ecotoxicology in Regulatory Decision-Making 30 August–4 September 2015 in Shepherdstown, West Virginia, USA. Several important publications came out of that Pellston including: Hall AT, Martin O, Belanger SE, Galay-Burgos M, Guiney PD, Maack G, Stubblefield B. 2017. New Approach for Weight-of-Evidence Assessment for Ecotoxicological Effects in Regulatory Decision-Making. Integrated Environ Assess and Manage. 13(4): 573–579. Following this trailblazing SETAC Pellston Workshop, the SETAC International Programs Committee took up the WOE charge for SETAC by sponsoring a series of Special Symposia Risk Assessment and the use of WOE for Chemical Management at several international SETAC meetings including SETAC Europe- Barcelona (2015), SETAC-AP Singapore (2016), SETAC Latin America Santos (2017), the Stockholm Convention Persistent Organic Pollutant Review Committee, Rome, Italy (2017) and SETAC-AP Daegu (2018),. Finally, these SETAC WoE efforts were formalized in 2018 with the development of a SETAC Technical Issue Paper: Weight-of-Evidence in Environmental Risk Assessment of Chemicals. It is clear that SETAC has the expertise necessary to advance the science of WoE and is well positioned to develop additional scientific guidance on this topic.

Goals and Objectives for Developing a SETAC Guidance Document on WoE

Based on SETAC's international experience with applying WoE for Chemicals Management programs in various regions of the world, it is clear that there are many different WoE approaches available to both the practitioner and the regulator. Some of these approaches are highly prescriptive and well-developed especially in the developed economies while the idea of using WoE in many developing countries or less economically developed country may exist in concept only or not at all. We have reviewed the recent OECD Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment document (OECD ENV/JM/HA (2019)8). While we believe it is a valuable contribution and offers a conceptual framework, there is very little specific guidance on the process of assessing chemicals and only a tangential mention of the importance of a tiered WoE approach. The value of using a reliable tiered approach for WoE emerged as a key finding from our SETAC-sponsored symposia on Ecological risk assessment and WoE. We believe there is an opportunity for a useful SETAC contribution by illustrating how tiered approach for chemicals involves a progressive WoE approach. The precedent that come to mind is Risk-Based Corrective Action (RBCA) which has been described in OECD Standard Guide for Risk-Based Corrective Action (ASTM E2081 - 00(2015). This ASTM Standard lays out the decision process but lacks a WoE approach. We believe that a SETAC Guidance document that marries the concept of a tiered strategy with WoE underpinnings, with an emphasis on chemical management and global application would be a significant contribution.

SETAC envisions a critical need to establish common philosophies and fundamentals which can provide simplified and practical guidance for consistently using WoE in Chemicals Management, especially in developing countries where formal guidance may not exist. Therefore, our objective is to develop a SETAC WoE Guidance Document that:

1. Acknowledges that there can be more than one method for establishing WoE from very simplistic to very complex but also recognizes that there are basic common philosophies and fundamentals which if followed can be used to implement a WoE approach to Chemicals Management regardless of available resources and regulatory structures,
2. Allows for the integration of various types of scientific information including basic ecotoxicology fate and effects data, advancing ecotoxicology risk assessment approaches and newer emerging data from genomics and Adverse Outcome pathways into useful decision-making tools,
3. Provides a transparent mechanism for communicating *a priori* the decision-making process to be used in Chemicals Management so that the method selected and the decisions made can be very clearly understood and accepted by all stakeholders in achieving specific protection goals.

The overall goal of this SETAC Guidance Document is to focus on developing direction related to the use of WoE in Chemicals Management including prioritization. The document will specifically exclude applications of WoE for other contexts including site-specific risk assessments, mechanistic risk assessments, water- and sediment-quality standards assessments etc. Furthermore, a special emphasis of this document will be devoted to enabling a WoE approach that can be universally implemented in developing countries.

Structures for the SETAC WoE Guidance Document

The document will describe the prevalent controlling values that should be used when developing a WoE approach for Chemicals Management. These should include first, the need for a clear Problem Formulation step which defines the specific issue for which evidence is needed and a mechanism for gathering input and consensus from all stakeholders. Secondly, there must be a conceptual design including a step-by-step method for how all the evidence will be collected, evaluated, and eventually weighted. This conceptual design must be clearly understood and accepted by all stakeholders. Third, the document should include guidance on how to recognize and address various types of scientific bias, the advantages of using a tiered testing approach to data generation and application, and approaches for treating data uncertainty including both a lack of data as well as potential ambiguities associated with established ecotoxicology and environmental fate data. Finally, the document will focus on providing "best available tools" for transparently documenting and communicating all WoE-based decisions so that they are reproducible and plainly comprehended by all stakeholders.

Strategies for the SETAC WoE Guidance Document-Use of case Studies

SETAC has considerable experience through our multiple interactions with Geographic Units (GUs) for tackling real world problems like using WoE to improve Chemicals Management. We have found that using rea-world examples are more tangible and meaningful to our members and stakeholders by providing concrete applications to knowledge and skills they learn through reading peer-reviewed papers and regulations.

Real world examples demonstrate the complexity and unpredictability of issues like using WoE for improved Chemicals Management, and as such, can stimulate critical thinking. They also highlight the

need for an inter- and multi-disciplinary approach to problem solving. Further, using examples from the real world demonstrates that, oftentimes, there is no perfect solution to a given problem. But, in doing so, gets scientists and regulators alike thinking about solutions, rather than just focusing on problems.

A key aspect of this proposed SETAC WoE Guidance Document will be the inclusion of various case studies to provide a context-rich opportunity for the reader to learn about the real problems in this area and to think critically about potential solutions to these problems. For instance, case studies such as the use of the Bioaccumulative Assessment Tool (BAT) for evaluating bioaccumulation potential of chemicals will be used illustrate how to integrate various LOEs in a transparent and quantitative WoE approach using a tiered testing strategy that can be implemented at various levels of sophistication within various regulatory frameworks.

Selected References and SETAC WOE Meetings and Symposia

Hall AT, Martin O, Belanger SE, Galay-Burgos M, Guiney PD, Maack G, Stubblefield B. 2017. New Approach for Weight-of-Evidence Assessment for Ecotoxicological Effects in Regulatory Decision-Making. Integrated Environ Assess and Manage. 13(4): 573–579. DOI: 10.1002/ ieam.1936.

[SETAC] Society of Environmental Toxicology and Chemistry. 2018. Technical Issue Paper: Weight-of-Evidence in Environmental Risk Assessment of Chemicals. Pensacola (FL): SETAC. 8 pp.

SETAC Pellston Workshop: Improving the Usability of Ecotoxicology in Regulatory Decision-Making
30 August–4 September 2015 | Shepherdstown, West Virginia, USA
[HYPERLINK "https://www.setac.org/resource/resmgr/publications_and_resources/Usability_Workshop_Executive.pdf"] and [HYPERLINK "https://setac.onlinelibrary.wiley.com/hub/issue/10.1002/ieam.v13.4/" \t "_blank"]

Chemical Risk Assessment Approach and Needs for the Latin America Region 7 September 2017, Santos, São Paulo, Brazil

Chemical Risk Assessment Approach and Needs for the Asia-Pacific Region 16 September 2016, Singapore

Guiney, P.D. Incorporating Advancements in the Science of WOE to Evaluate POPs in the existing context of the Stockholm Convention. Stockholm Convention Persistent Organic Pollutant Review Committee (POPRC) Meeting October 19, 2017 Rome, Italy

Application of Weight-of-Evidence (WoE) in Risk-Based Ecological Assessment Frameworks Special Symposium May 3, 2015 Barcelona, Spain as part of the 2015 SETAC Europe Meeting